

**CLAIMS:**

1. A measurement system for use in detecting a predetermined condition of a patient's ear indicative of a certain disease, the system comprising:

(a) an optical measuring unit configured and operable for irradiating a region of interest in the patient's ear with incident light including at least two different wavelengths, detecting light responses of the region of interest to said at least two different wavelengths, and generating measured data indicative thereof, said at least two different wavelengths being selected such that the light response of the region of interest to at least one first wavelength is substantially independent of said predetermined condition and the light response to at least one second wavelength is affected by said predetermined condition; and

(b) a control unit configured and operable for controlling operation of the optical measuring unit, and for receiving the measured data and processing it to generate output data indicative of whether or not said predetermined condition exists, the control unit comprising a memory utility for storing predetermined reference data indicative of the light response of the region of interest while in a healthy condition of the ear; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by determining a relation between the measured light responses and the corresponding reference data.

2. The system of Claim 1, wherein said at least two wavelengths include the at least one first reference wavelength in at least one of the following wavelength ranges: about 700-900nm and about 1420-1480nm, and the at least one second operating wavelength in at least one of the following ranges: about 1200-1400nm and 1500-1700nm, the system being therefore operable for detecting a serous otitis media (SOM) condition of the patient's ear.

3. The system of Claim 2, wherein said wavelengths include at least one additional second wavelength in at least one of the following wavelength ranges: about 540-

550nm and 570-580nm, the system being therefore operable to detect an acute otitis media (AOM) condition.

4. The system of Claim 2, wherein said wavelengths include at least one additional second wavelength in at least one of the following wavelength ranges: about 540-560nm and 570-580nm, the system being therefore operable to detect a change in a hemoglobin level in the region of interest.
5. The system of Claim 1, wherein the reference data is indicative of a relation between the light responses of the healthy ear to said at least two different wavelengths.
- 10 6. The system of Claim 5, wherein the measured data is in the form of a relation between the light responses of the region of interest in the patient's ear to said at least two different wavelengths.
7. The system of Claim 2, wherein the reference data is indicative of the light response for the operating wavelength as a function of the light response for the 15 reference wavelength corresponding to the healthy condition; the control unit being configured and operable to process the measured data to determine the light response for the operating wavelength as a function of the light response for the reference wavelength,  $I^{(w)}_{\lambda_{oper}}=f_1(I^{(w)}_{\lambda_{ref}})$ , and determine a difference between the reference and measured data indicative of whether fluid media exists in the region 20 of interest being therefore indicative of the SOM condition.
8. The system of Claim 4, wherein the reference data is indicative of the light responses for the second operating wavelengths as functions of the light response for the reference wavelength corresponding to the healthy condition; the control unit being configured and operable to process the measured data to determine the light response for the second operating wavelength as a function of the light response for the reference wavelength,  $I^{(w)}_{\lambda_{oper}}=f_1(I_{\lambda_{ref}})$ , and the light response for the additional second operating wavelength as a function of the light response for the reference wavelength,  $I^{(h)}_{\lambda_{oper}}=f_2(I_{\lambda_{ref}})$ , and determine differences between the reference and measured data indicative of whether fluid media exists in the region 25 of interest and whether there is a change in the hemoglobin concentration as 30

compared to that of the healthy condition, being thereby indicative of the AOM condition.

9. The system of Claim 1, wherein the reference data is indicative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient.

10. The system of Claim 1, wherein said measuring unit is configured and operable for spectrometric measurements, the measured data being therefore in the form of the light response of the region of interest as a function of wavelengths of the incident light.

11. The system of Claim 1, wherein said measuring unit is configured and operable for spectrometric measurements, the measured data being therefore derived for said at least two different wavelengths from spectral data in the form of the light response of the region of interest as a function of wavelengths of the incident light.

12. The system of Claim 9, wherein said measuring unit is configured and operable for spectrometric measurements, the measured data being therefore in the form of the light response of the region of interest as a function of wavelengths of the incident light.

13. The system of Claim 1, wherein the measuring unit comprises an illumination unit configured and operable to generate said incident light, a light detection unit for detecting light of said at least two wavelengths and generating the measured data; and a light directing unit for directing the incident light to the region of interest and collecting light reflected from the region of interest, the light directing unit comprising an optical fiber arrangement.

14. The system of Claim 13, wherein the light directing unit comprises a spectral filtering unit for separating said at least two wavelengths from the collected light.

15. The system of Claim 13, wherein the fiber arrangement comprises at least one illuminating fiber for transmitting the incident light to the region of interest and at least one light collecting fiber for collecting and transmitting the reflected light to the detection unit.

**16.** The system of Claim 15, wherein each of said at least two fibers has a predetermined numerical aperture such that for a given distance between the measuring unit and the region of interest said at least two wavelengths illuminate substantially the same spot in the region of interest and reflected light is collected 5 substantially from the illuminated spot.

**17.** The system of Claim 13, wherein the fiber arrangement is configured to provide substantially the same numerical aperture of light incidence onto the region of interest and light collection from the region of interest.

**18.** The system of Claim 15, wherein the fiber arrangement is configured such that, 10 for a given distance between the measuring unit and the region of interest, output of said at least one illuminating fiber presents a point-like light source for a predetermined spot size in the region of interest.

**19.** The system of Claim 3, wherein the measuring unit comprises an illumination unit configured and operable to generate the incident light including the at least 15 three different wavelengths, a light detection unit for detecting light of said at least three wavelengths and generating the measured data; and a light directing unit for directing the incident light to the region of interest and collecting light reflected from the region of interest, the light directing unit comprising an optical fiber arrangement.

**20.** The system of Claim 19, wherein the light directing unit comprises and a spectral filtering unit.

**21.** The system of Claim 19, wherein the illumination unit comprises a first light source generating light including the first reference wavelength in the range of about 1420-1480nm and the second operating wavelength in the range of about 25 1500-1700, and a second light source generating light including the additional second wavelength in the range of 540-580nm; and said detection unit comprises a first detector for detecting light of the first and second wavelength ranges, and a second detector for detecting light of the additional second wavelength range.

**22.** The system of Claim 12, wherein the measuring unit is configured for determining a reference spectrum indicative of the light intensity illuminating the region of interest as a function of wavelengths of the incident light.

**23.** The system of Claim 22, wherein the processing and analyzing utility is 5 preprogrammed for processing the measured data by selecting a certain part of the measured data within at least one range of a predetermined light spectrum and applying a predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and to generate output data indicative of 10 association between the determined parameter value and the reference data.

**24.** The system of Claim 23, wherein the processing of the measured spectral data comprises normalizing the measured spectral data by said reference spectrum, thereby obtaining a normalized reflectivity spectrum which then undergoes said processing by the predetermined model.

15 **25.** The system of Claim 24, wherein the processing and analyzing of the measured data comprises optimizing the normalized reflectivity spectrum by further normalizing it by a certain wavelength  $\lambda_0$  within said selected spectrum range, such that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ , thereby obtaining a relative spectrum that undergoes said processing with the 20 predetermined model.

**26.** The system of Claim 23, wherein said at least one selected range of the predetermined light spectrum is defined by the patient's condition to be detected.

25 **27.** The system of Claim 23, for use in determining the existence of otitis media condition in the patient's ear, the predetermined light spectrum being within a range of 300-1700nm.

**28.** The system of Claim 27, wherein the selected range of the predetermined light spectrum includes a range of 500-650nm.

**29.** The system of Claim 27, wherein the selected range of the predetermined light spectrum includes a range of 800-950nm.

**30.** The system of Claim 28, wherein the selected range of the predetermined light spectrum includes a range of 800-950nm.

**31.** The system of Claim 25, wherein said processing with the predetermined model comprises applying a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data, said ratio presenting said at least one measurable parameters indicative of the patient's condition.

**32.** The system of Claim 25, wherein said processing with the predetermined model comprises applying a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data, said ratio being scalable to determine said at least measurable parameter indicative of the patient's condition.

**33.** The system of Claim 23, wherein said control unit is configured as an expert system capable of timely analyzing the calculated measurable parameters and optimizing the model accordingly.

**34.** The system of Claim 27, wherein the measuring unit is configured for determining a reference spectrum indicative of the light intensity illuminating the region of interest as a function of wavelengths of said predetermined incident light.

**35.** The system of Claim 34, wherein the processing of the measured spectral data comprises normalizing the measured spectral data by said reference spectrum, thereby obtaining a normalized reflectivity spectrum which then undergoes said processing by the predetermined model.

**36.** The system of Claim 35, wherein the processing and analyzing of the measured data comprises optimizing the normalized reflectivity spectrum by further normalizing it by a certain wavelength  $\lambda_0$  within said selected spectrum range, such that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ , thereby obtaining a relative spectrum that undergoes said processing with the predetermined model.

– 42 –

37. The system of Claim 36, wherein said processing with the predetermined model comprises applying to a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data.

38. The system of Claim 36, wherein said processing with the predetermined model comprises applying a Likelihood Algorithm to the relative spectrum, calculating a feature vector as a function of wavelengths within said selected range, and calculating a log-likelihood ratio between the feature vector of the relative spectrum and that of the reference data, said ratio being scalable to determine said at least measurable parameter indicative of the patient's condition

39. The system of Claim 37, wherein said processing of the relative spectrum comprises determining two measurable parameters indicative of the existence in the patient's ear of, respectively, serous otitis media (SOM) and acute otitis media (AOM).

40. The system of Claim 35, wherein said normalizing of the measured spectral data by said reference spectrum comprises presenting the measured spectrum  $E_j(\lambda, t)$  and the reference spectrum  $W_j(\lambda, t)$  as, respectively,

$$E_j(\lambda, t) = A I_j(\lambda, t) R_E(\lambda) D_j(\lambda, t) \text{ and } W_j(\lambda, t) = B I_j(\lambda, t) R_W(\lambda) D_j(\lambda, t)$$

wherein  $j$  is the number of the measuring unit,  $t$  is the time,  $\lambda$  is the wavelength of incident light,  $A$  and  $B$  are unknown amplitudes,  $I_j(\lambda, t)$  is the illumination spectrum of light source for the measuring unit  $j$ ;  $D_j(\lambda, t)$  is the light response spectrum of a detector assembly of for measuring unit  $j$ ;  $R_E(\lambda)$  is the reflectivity spectrum of the region of interest; and  $R_W(\lambda)$  is the reflectivity of a reference surface used in obtaining said reference spectrum, the normalized reflectivity spectrum being thus determined as:

$$R(\lambda) = E_j(\lambda, t) / W_j(\lambda, t) = C R_E(\lambda) / R_W(\lambda),$$

wherein parameter  $C$  is a light signal amplitude depending *inter alia* upon a signal integration time and a distance between the measuring unit and the region

– 43 –

of interest.

**41.** The system of Claim 40, wherein the processing and analyzing of the measured relative spectrum comprises optimizing the normalized reflectivity spectrum by further normalizing it by a certain wavelength  $\lambda_0$  within said selected spectrum range, such that all the light intensities are measured relative to the intensity at wavelength  $\lambda_0$ , thereby obtaining a relative spectrum in which the effect of parameter  $C$  is eliminated, said processing with the predetermined model being applied to the relative spectrum.

**42.** The system of Claim 41, wherein said further normalizing comprises setting the relative spectrum  $r(\lambda) = R(\lambda) / R(\lambda_0)$  so that  $r(\lambda_0) = 1$ .

**43.** The system of Claim 41, wherein the selected value of  $\lambda_0$  is the center of the wavelength range of said predetermined incident light.

**44.** The system of Claim 43, wherein the creation of the reference data and the model comprises:

- sampling a spectrum  $r(\lambda)$  at certain discrete wavelengths, to generate a feature vector  $\underline{r} = \{ r(\lambda_n), n = 1, 2, \dots, N \}$ ;

- learning probability densities  $f(\underline{r} | A)$  and  $f(\underline{r} | B)$  for populations including (A) healthy ears and (B) infected ears; and

- defining said value or range of values as a threshold  $T_1$  chosen to achieve a desired level of sensitivity corresponding to the probability of correctly diagnosing the existence of the predetermined condition of the patient's ear.

**45.** The system of Claim 44, wherein the probability densities include Gaussian probability densities  $f(\underline{r} | A) = g(\underline{r}, \underline{\mu}_A, P_A)$  and  $f(\underline{r} | B) = g(\underline{r}, \underline{\mu}_B, P_B)$ , wherein  $g(\underline{r}, \underline{\mu}, P) = [2\pi \det(P)]^{-N/2} \exp [-1/2 (\underline{r} - \underline{\mu})^T P^{-1} (\underline{r} - \underline{\mu})]$ ,  $\underline{\mu} = \text{mean}(\underline{r})$ ,  $P = \text{covariance}(\underline{r}) = NxN$  matrix.

**46.** The system of Claim 45, wherein the processing and analyzing of the relative spectrum comprises processing the measured feature vector to determine said at least one measurable parameters  $L_1$  as the log-likelihood ratio:

$$L_1(\underline{x}) = 2 \log \{ f(\underline{x} | B) / f(\underline{x} | A) \}$$

- 44 -

$$= (\underline{x} - \underline{\mu}_A)^T P_A^{-1} (\underline{x} - \underline{\mu}_A) - (\underline{x} - \underline{\mu}_B)^T P_B^{-1} (\underline{x} - \underline{\mu}_B)$$

47. The system of Claim 46, wherein the processing and analyzing of the relative spectrum comprises determining the association between said ratio and the predetermined threshold value T1 indicative of the existence of the otitis media in  
5 the patient's ear.

48. The system of Claim 47, wherein said processing and analyzing provides for identifying wherein the otitis media includes serous otitis media (SOM) or acute otitis media (AOM).

49. The system of Claim 48, wherein the creation of said reference data and said  
10 model comprises defining said value or range of values as a threshold T2 chosen to achieve a desired level of sensitivity corresponding to the probability of correctly diagnosing the existence of the serous otitis media (SOM) and acute otitis media (AOM).

50. The system of Claim 49, wherein said processing and analyzing comprises:  
15 - processing the measured feature vector to determine another measurable parameter L2 as the log-likelihood ratio:

$$\begin{aligned} L2(\underline{x}) &= 2 \log \{ f(\underline{x} | B_2) / f(\underline{x} | B_1) \} \\ &= (\underline{x} - \underline{\mu}_{B1})^T P_{B1}^{-1} (\underline{x} - \underline{\mu}_{B1}) - (\underline{x} - \underline{\mu}_{B2})^T P_{B2}^{-1} (\underline{x} - \underline{\mu}_{B2}) \end{aligned}$$

- determining the association between said ratio L2 and the predetermined threshold  
20 value T2 indicative of whether the detected otitis media is SOM or AOM.

51. The system of Claim 1, wherein said measuring unit is configured as an optical probe for directing the at least two different wavelength to the region of interest along at least two separate channels, respectively, and directing the collected reflected light along at least one optical channel.

25 52. The system of Claim 51, wherein the optical probe comprises a fiber bundle including at least two illuminating fibers defining said at least two channels, and at least one collecting fiber defining said at least one collecting channel.

53. The system of Claim 52, wherein at least within a distal end of the probe, by  
30 which it is to be brought to the region of interest, the at least one collecting fiber is located within a region between the at least two illuminating fibers.

– 45 –

**54.** The system of Claim 53, wherein the collecting fiber has a cross section larger than the illuminating fiber.

**55.** The system of Claim 52, wherein the probe is configured to define an imaging channel.

5 **56.** The system of Claim 55, wherein at least within a distal end of the probe, by which it is to be brought to the region of interest, the fiber bundle is located in central region of the probe; said imaging channel being defined by at least one of the at least two illuminating fibers that transmits the light to the region of interest and a periphery region of the probe surrounding the fiber bundle for transmitting 10 the reflected from the region of interest.

**57.** The system of Claim 1, wherein said measuring unit is configured as an optical probe for transmitting light emanating from a target tissue in the region of interest along at least two separate optical channels.

15 **58.** The system of Claim 57, wherein the probe comprises a probe head and a speculum member removably fitted to a distal end of said probe head, wherein said probe head comprises light transmission unit for directing the incident light to said target tissue via a distal end of said speculum, and for directing light emanating from said target tissue along said at least two separate optical channels; and wherein said speculum member is adapted for positioning said distal end thereof proximate 20 to the target tissue.

**59.** The system of Claim 58, wherein said distal end of said speculum member comprises an optical aperture for enabling illuminating light and emanating light to pass therethrough from and to said optical probe.

25 **60.** The system of Claim 59, wherein said at least two separate optical channels comprise:

a first channel for enabling qualitative analysis of the collected light emanating from said target tissue; and

a second channel for enabling quantitative analysis of the collected light emanating from said target tissue.

**61.** The system of Claim 60, wherein said speculum member comprises an internal reflecting mirror for directing illuminating light from said light transmission means to said distal end.

5       **62.** The system of Claim 57, wherein said probe head comprises a beam splitter arrangement for splitting light traveling in a proximal direction from said distal end into said first channel and said second channel.

**63.** The system of Claim 62, wherein said beam splitter arrangement comprises a parabolic mirror having an aperture therein.

10      **64.** The system of Claim 63, wherein said aperture is configured for directing a first portion of said light traveling from said distal end therethrough along said first channel and towards an objective.

**65.** The system of Claim 64, wherein said objective comprises an eyepiece ocular.

**66.** The probe of Claim 64, wherein said objective comprises a suitable camera means for recording said image.

15      **67.** The system of Claim 63, wherein said parabolic mirror comprises an optical focusing element for directing a second portion of said light traveling from said distal end along said second channel and towards a light sensor.

20      **68.** The system of Claim 59, wherein said speculum member comprises a suitable first waveguide for directing illuminating light from said light transmission means to said distal end.

25      **69.** The system of Claim 68, wherein said first waveguide is in the form of a first layer of material having waveguiding properties comprised in said speculum member, said first layer having a transmitting face proximate to said distal end, and a first mating face in optical communication with said transmitting face and adapted for enabling illumination light from said light transmission means to pass therethrough to said transmitting face when said speculum member is fitted to said probe head.

**70.** The system of Claim 69, wherein said light transmission means comprises a second mating face configured to provide optical communication between said light

transmission means and said first mating face when said speculum member is fitted to said probe head.

71. The system of Claim 69, wherein said first channel is in the form of a proximal aperture comprised in said probe head, said aperture being configured for directing a first portion of said light traveling from said distal end therethrough and towards an objective.

72. The system of Claim 70, wherein said first channel is in the form of a proximal aperture comprised in said probe head, said aperture being configured for directing a first portion of said light traveling from said distal end therethrough and towards an objective.

73. The system of Claim 72, wherein said objective comprises an eyepiece ocular.

74. The system of Claim 72, wherein said objective comprises a suitable camera means for recording said image.

75. The system of Claims 69, wherein said first layer is made from PMMA.

76. The system of Claims 60, wherein said second channel comprises a suitable second waveguide for directing light from said distal end towards a light sensor.

77. The system of Claims 68, wherein said second waveguide is in the form of a second layer of material having waveguiding properties comprised in said probe head, said second layer having a second receiving face proximate to said distal end, and a second transmitting face in optical communication with said second receiving face and adapted for enabling light from outside of said distal end to pass therethrough from said second receiving face to said second transmitting face.

78. The system of Claim 77, wherein said second transmitting face is in optical communication with a suitable light sensor.

79. The system of Claim 77, wherein said second layer is made from PMMA.

80. The system of Claim 78, wherein said second layer is made from PMMA.

81. The system of Claim 77, wherein said light sensor is operatively connected to a suitable spectrometer.

82. The system of Claim 79, wherein said light sensor is operatively connected to a suitable spectrometer.

**83.** The system of Claim 80, wherein said light sensor is operatively connected to a suitable spectrometer.

**84.** The system of Claim 57, wherein said speculum member is disposable after use with one patient.

5   **85.** The system of Claim 57, wherein said speculum member is adapted for positioning said distal end thereof within an ear canal of a patient proximate to the ear drum thereof.

10   **86.** The system of Claim 57, wherein said speculum member is adapted for positioning said distal end thereof within a vaginal canal of a patient proximate to the ear drum thereof.

**87.** The system of Claim 57, wherein said speculum member further comprises a plug removably fitted to said distal aperture, said plug configured to diffusely reflect incident light thereon from said light transmission means in a known manner.

15   **88.** A measurement system for use in determining a patient's condition, the system comprising:

      (a) an optical measuring unit operable for applying spectral measurements to the region of interest in a patient's body with predetermined light spectrum and producing measured spectral data indicative thereof; and

20   (b) a control unit for receiving and processing the measured data to generate output data indicative of the measurement results, the control unit comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by selecting a certain part of the measured data within at least one range of the predetermined light spectrum and applying a predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and to generate said output data

25

30

indicative of association between the determined parameter value and the reference data.

89. An optical probe for transmitting light emanating from a target tissue in a region of interest along at least two separate optical channels, comprising a probe head and 5 a speculum member removably fitted to a distal end of said probe head, wherein:

    said probe head comprises light transmission means for directing an illuminating light to said target tissue via a distal end of said speculum, and means for directing light emanating from said target tissue along at least two separate optical channels; and wherein

10      said speculum member is adapted for positioning said distal end thereof proximate to the target tissue.

90. A control unit configured for receiving spectral measured data from a region of interest on a patient's body, and processing the received data to generate output data indicative of the patient's condition, the control unit comprising a memory utility 15 for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient and for storing the reference spectrum; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by:

20      - obtaining a relative spectral, said obtaining including selecting a part of the measured data within at least one range of the predetermined light spectrum and normalizing said selected part of the measured data by the reference spectrum;

25      - applying a predetermined model to the relative spectrum to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

91. A measurement system for use in determining the patient's condition, the 30 system comprising an optical measuring unit operable for carrying out spectral

measurements, the measuring unit comprising a light source system for generating light of predetermined wavelengths, a detector for collecting light impinging thereon and generating data indicative thereof, said measuring unit comprising a plug that is shiftable between its operative and inoperative positions so as to be, 5 respectively, in and out of the optical path of light propagating from the light source system and having a highly diffusely reflective surface, the measuring unit being selectively operable to apply spectral measurements to said surface and obtain reference spectrum data indicative of the reflectance of incident light from said surface and to apply spectral measurements to the region of interest on patient's 10 body to obtain measured spectral data indicative of the reflectance of the incident light from the region of interest.

92. The system of Claim 91, comprising a control unit for receiving and processing the measured data to generate output data indicative of the measurement results, the control unit comprising a memory utility for storing predetermined reference data 15 representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient and for storing the reference spectrum; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by

- obtaining a relative spectral, said obtaining including selecting a part of the 20 measured data within at least one range of the predetermined light spectrum and normalizing said selected part of the measured data by the reference spectrum;
- applying a predetermined model to the relative spectrum to determine a corresponding value of said at least one predetermined measurable 25 parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

93. A program storage device readable by machine, tangibly embodying a program of instructions executable by the machine to perform method steps for receiving 30 spectral data measured from a region of interest on a patient's body, and processing

the received data to generate output data indicative of the patient's condition, the storage device comprising a memory utility for storing predetermined reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient and for 5 storing the reference spectrum; a data processing and analyzing utility preprogrammed for processing and analyzing the measured data by obtaining a relative spectral, said obtaining including selecting a part of the measured data within at least one range of the predetermined light spectrum and normalizing said selected part of the measured data by the reference spectrum; applying a predetermined model to the relative spectrum to determine a corresponding value of 10 said at least one predetermined measurable parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

94. A computer program product comprising a computer useable medium having 15 computer readable program code embodied therein for processing spectral data measured from a region of interest on a patient's body, the computer program product comprising: a data processing and analyzing utility for selecting a part of the measured data within at least one predetermined range of a light spectrum used in the measured data and utilizing a reference spectrum to normalize said selected 20 part of the measured data to obtain a relative spectrum, applying a predetermined model to the relative spectrum and utilizing reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient, to thereby determine a value of 25 said at least one predetermined measurable parameter corresponding to the measured data and generate output data indicative of association between the determined parameter value and the reference data.

95. A method for processing spectral measured data to enable determination of a patient's condition, the method comprising processing the spectral measured data indicative of reflection of predetermined incident light from a region of interest as a 30 function of wavelengths of the incident light; said processing comprising selecting a

predetermined part of the measured spectral data corresponding to at least one range of the predetermined incident light, normalizing the selected measured data to obtain a relative spectrum, and applying a predetermined model to the relative spectrum to determine a corresponding value of at least one predetermined measurable parameter and to generate output data indicative of association between the determined parameter value and preset reference data, said reference data being representative of a value or a range of values for said at least one predetermined measurable parameter corresponding to a healthy condition of a patient.

96. A method for use in detecting an SOM or AOM condition of a patient's ear, the method comprising illuminating a region of interest in the ear by at least two wavelengths, detecting light responses of the region of interest to said at least two different wavelengths, and generating measured data indicative thereof, said at least two different wavelengths being selected such that the light response of the region of interest to at least one first wavelength is substantially independent of said condition and the light response to at least one second wavelength is affected by said condition.

97. A method for use in detecting an SOM or AOM condition of a patient's ear, the method comprising illuminating a region of interest in the middle ear by at least two wavelengths, detecting light responses of the region of interest to said at least two different wavelengths, and generating measured data indicative thereof, said at least two different wavelengths being selected such that at least one first wavelength satisfies at least one of the following: is substantially absorbable by water or is substantially transmittable by water, the light response to said first wavelength being therefore substantially independent of said condition, and the at least one second wavelength being partially absorbable by water the light response to said at least one second wavelength being therefore affected by said condition.

98. A method for use in detecting an SOM or AOM condition of a patient's ear, the method comprising illuminating a region of interest in the middle ear by at least two wavelengths, detecting light responses of the region of interest to said at least two different wavelengths, and generating measured data indicative thereof, said at

least two different wavelengths being selected such that at least one first wavelength satisfies at least one of the following: is substantially absorbable by water or is substantially transmittable by water, the light response to said first wavelength being therefore substantially independent of said condition, and the at 5 least one second wavelength being partially absorbable by water the light response to said at least one second wavelength being therefore affected by said condition, a change in the intensity of the detected light of said at least one second wavelength from a corresponding intensity for a healthy condition being indicative of the SOM or AOM condition, and a decrease in the intensity of the detected light to said at 10 at least one second wavelength from that corresponding to the SOM condition being indicative of the AOM condition.

**99.** A method for use in detecting an SOM or AOM condition of a patient's ear, the method comprising illuminating a region of interest in the middle ear by at least three wavelengths, detecting light responses of the region of interest to said at least three different wavelengths, and generating measured data indicative thereof, said at 15 least three different wavelengths being selected such that at least one first wavelength satisfies at least one of the following: is substantially absorbable by water and substantially non-absorbable by hemoglobin, and is substantially transmittable by water and substantially non-absorbable by hemoglobin; the light response of the region of interest to said at least one first wavelength being therefore substantially independent of said condition, the at least two second wavelengths including a wavelength that is partially absorbable by water and a wavelength that is relatively highly absorbable by hemoglobin the light response to said at least two second wavelengths being therefore affected by said condition.

**100.** A method for use in determining a patient's condition, the method comprising:

- (i) providing reference data representative of a value or a range of values for at least one predetermined measurable parameter corresponding to a healthy condition of a patient, and a certain reference spectrum corresponding to

reflectance of a predetermined light spectrum from a reference highly reflective surface;

- (ii) applying spectral measurements to a region of interest on the patient's body with predetermined light spectrum and producing measured spectral data indicative thereof; and
- (iii) processing the measured data to generate output data indicative of the measurement results, said processing comprising selecting a part of the measured data within at least one range of the predetermined light spectrum and applying a predetermined model to the selected part of the measured data to determine a corresponding value of said at least one predetermined measurable parameter for the measured patient and generate said output data indicative of association between the determined parameter value and the reference data.

5

10